K110179
Pg. 1 of 7

510(k) Summary for InControl InTone

FEB 2 2 2012

Submitter:	InControl Medical, LLC
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Establishment Registration #:	to be registered following 510(k)
Submission Contact:	Michael J. Leigh, consultant 12715 Falcon Drive Brookfield, Wisconsin 53005 Ph: (262) 957-6797
Trade Name:	InControl InTone
Predicate Device:	Otto Bock STIWELL med, K080950 MyoTrac Infiniti, K053434 Hollister evadri, K050483
Common Name:	Stimulator, Electrical, Non-Implantable, for Incontinence

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
876.5320	KPI	Non-implanted electrical continence device	II

Device Description:

The device includes three parts; an insertion probe and a hand-held control unit. The insertion probe features an inflatable balloon that provides more adaptable fit for intra-vaginal use. The probe includes stainless steel electrodes to deliver electro-stimulation. The hand-held control and display device records, stores, and displays the results of electro-stimulation and patient generated pelvic floor exercises. It allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. It also stores data on contraction pressure for later review. The PC application allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

Intended Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Performance Data:

Complete EMC, electrical, mechanical, safety (operator and patient), temperature/humidity, and software testing demonstrate compliance with applicable standards. The results demonstrate that the InControl InTone device is in compliance with the guidelines and standards referenced in the FDA reviewer's guides, and that it performed within its specifications and functional requirements for the device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with FDA requirements.

Feature/ Function	InControl InTone (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Labeling					
Intended Use An explicit description of all clinical functions performed by the device, **Indications for Use** Explain when the device is to be clinically used and the intended patient population	The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.	The STIWELL med4 is a neuromuscular electronic stimulator for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions: • Acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of the pelvic floor muscles. • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles. As a biofeedback device the STIWELL med4 is indicated for the following conditions: • Biofeedback, relaxation and muscle re-education purposes.	Treatment of urinary incontinence EMG biofeedback The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.	The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary or fecal (electromyographic biofeedback) incontinence.	Equivalent
Warnings or Precautions	(see product labeling)	(see product labeling)	(see product labeling)	(see product labeling)	Equivalent

Contraindications Explain when the device is not to be clinically used	• This device is not intended for diagnostic purposes or critical patient monitoring. • The device is not defibrillator proof. • The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance. • Do not use if patient has symptoms of an active urinary tract infection. • Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms. • Do not use if patient has undiagnosed pain. • Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation. • Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings. • Do not use if patient is currently pregnant or attempting to get pregnant. • Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit. • Do not use if the patient has irregular menstrual bleeding cycles. • Do not use if the patient has a history or symptoms of urinary retention. • Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Do not use if the patient has overflow incontinence caused by evacuation problems. • Do not use if the patient has severe urine retention in the upper urethras. • Do not use if the patient has complete peripheral denervation of the pelvic floor. • Do not use if the patient has an intestinal clamp.	• Patients with pacemakers or other electronic emitters. • No stimulation in the proximity of metal implants. • Pregnancy • Feverish or infectious diseases • Skin disorders subject to inflammation or tumors in the stimulation area, as well as thrombosis or phlebitis • Patients with extra-urethral incontinence (fistula, ectopic urethra) • Patients with overflow incontinence caused by evacuation disorders • Patients with serious urine retention in the upper urethra • Patients with total peripheral denervation of the pelvic floor • Patients with intestinal clamps	• Patients with an implanted electronic device (for example cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained. • Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions • Stimulation should not be applied over cancerous lesions • Not for use with patients with undiagnosed pain conditions. • Do not use if you have symptoms of bladder infection. • Do not use with diminished mental capacity or physical competence limiting the use of the device • Safety of powered muscle stimulators during pregnancy has not been established.		Equivalent
Labeling Summary Clarity to insure safer or more effective use	User Manual	User Manual	User Manual	User Manual	Identical (to all)
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	4/5 AA nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent

Method of line current isolation	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Patient leakage current	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current or voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic No-Load Trip?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery**	 Yes Yes	 Yes Yes	 Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	dual phase, rectangular pulses	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Mixed** **Stress** **Urge**	 50 Hz - -	 35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Within range (of MyoTrac, Hollister)
Pulse width **Mixed** **Stress** **Urge**	 200 μs/phase - -	 300 μs/phase 500 μs/phase	0.2 ms	0.3 or 1 ms	Within range
Time **On** **Off**	 20 secs 10 secs	 9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	 2 - 20 secs 2 - 50 secs	 1 - 80 secs 0 - 80 secs	Equivalent
Total Session Time	12 mins	5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)	50 Vdc	50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)	100 mA	100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)	50 μC	50 μC	60 μC	Unknown	Identical (to Otto Bock)
Electrode surface area	10.5 cm^2 x 2	21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density	4.7 mA/ cm^2	4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical
Maximum power density (500Ω)	14.3 μW/ cm^2	23.5 μW/ cm^2	Various, 11.32 μW/ cm^2 to 22.84 μW/ cm^2	Unknown	Equivalent
Biofeedback	Air pressure, 0 - 2 psi	EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)
Materials					

K110179
pg 5 of 7

Dimensions	8 x 5 x 4 inches	175 x 95 x 30 mm	102 x 152 x 51 mm	100 x 70 x 130 mm	Equivalent
Control housing	ABS plastics	plastics	plastics	plastics	Equivalent
Insertion material	Silicone, plastics	plastics	plastics	plastics	Equivalent
Packaging or Expiration Dating	1 year for insertion unit	N/A	N/A	N/A	
Sterilization	N/A	N/A	N/A	N/A	
User Interaction and Software					
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Identical (to all)
Patient Interaction: Functions Controllable An explanation of how the device interacts with the patient.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.				Equivalent
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, programming can only be changed by clinician	None, programming is locked by clinician	None, programming is locked by clinician		Equivalent (to Otto Bock, MyoTrac)
Override	Yes	Yes			Identical (to Otto Bock)
Patient Interaction: Operator Requirements Knowledge or training required of the operator,	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Identical (to all)
Software Level of Concern A statement indicating the Level of Concern and a description of the rationale for that level.	Moderate				

K110179
Pg 6 of 7

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Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	Nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current of voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery**	 Yes Yes	 Yes Yes	 Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	dual phase, rectangular pulses	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Mixed** **Stress** **Urge**	50Hz - -	 35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Identical (to MyoTrac, Hollister)
Pulse width **Mixed** **Stress** **Urge**	200 µs/phase - -	 300 µs/phase 500 µs/phase	0.2 ms	0.3 or 1 ms	Within range
Time **On** **Off**	 20 secs 10 secs	 9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	 2 - 20 secs 2 - 50 secs	 1 - 80 secs 0 - 80 secs	Within range
Total Session Time	12 mins	5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)	50 Vdc	50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)	100 mA	100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)	50 µC	50 µC	60 µC	Unknown	Identical (to Otto Bock)
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Biofeedback	Air pressure, 0 2 psi	EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)

K110179
pg. 7 of 7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

InControl Medical, LLC
% Mr. Michael J. Leigh
Consultant
12715 Falcon Drive
BROOKFIELD WI 53005

FEB 2 2 2012

Re: K110179
Trade/Device Name: InControl InTone
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: January 24, 2011
Received: January 31, 2012

Dear Mr. Leigh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110179

Device Name: InControl InTone

Indications For Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110179